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Recce Ltd (ASX: RCE)

Ahead of WHO's "priority pathogen" list

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Share Price: A$0.27

Speculative Buy

Higher Risk

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- The World Health Organisation (WHO) has published a list of the 12 bacteria which pose the greatest threat to human health because they are resistant to antibiotics. WHO's stated objective in compiling the list of "priority pathogens" is to spur governments to put in place policies to incentivise the development of new drugs.
- The most critical group includes multi-drug resistant bacteria that pose a particular threat in hospitals and nursing homes (bloodstream infections and pneumonia). Other high to medium priority bacteria cause gonorrhoea and food poisoning.
- We note with interest, that RCE has used their patented RECCE® synthetic-polymer antibiotics in in-vitro and/or in-vivo tests on 7 out of 12 listed bacteria (either the bacterium itself or a closely related bacterium). **The pre-clinical (animal) testing to determine the ability of the RECCE® 327 antibiotic to treat sepsis (blood infection) is particularly relevant.**

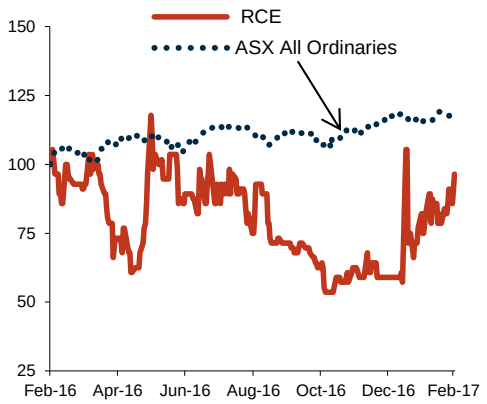
WHO's list of "priority pathogens" and RCE activity

Category	Bacteria	Recce activity
Critical: multi-drug resistant	*Pseudomonas aeruginosa*	Active in-vitro against RCE's own superbug of this bacterium
	Enterobacteriaceae	Active in-vivo (mice) against a member of this family CRE *E.coli*
	Acinetobacter baumannii	Not tested
High priority	*Enterococcus faecium*	Active in-vitro against a closely related species, *Enterococcus faecalis*
	Staphylococcus aureus	Active both in-vitro and in-vivo
	Heliobacter pylori	Active both in-vitro and in-vivo against three strains (2 of which were superbugs)
	Campylobacter	Not tested
	Salmonellae	Not tested
	Neisseria gonorrhoeae	Active in-vitro
Medium priority	*Streptococcus pneumoniae*	Active in-vitro against related superbug *Klebsiella pneumoniae*
	Haemophilus influenze	Not tested
	Shigella	Not tested

Source: Guardian newspaper, Company, compiled by State One Stockbroking

"*Without effective drugs, doctors cannot treat patients. Within a generation, without new antibiotics, deaths from drug resistant infection could reach 10 million pa. Without new medicines to treat deadly infection, lifesaving treatments like chemotherapy and organ transplant, and routine operations like caesareans and hip replacements will be potentially fatal*".
Tim Jinks, Wellcome Trust

- RCE is on-track for a pre- Investigational New Drug (IND) meeting with the US Food and Drug Administration (FDA) in April 2017, and is targeting to submit the IND application in late July. Note: an IND is a request for authorisation from the FDA to administer an investigational drug or biological product to humans. **Depending on the application approval process, we expect that RCE could be in a position to commence with clinical human trials (Phase 1- Safety) by the December quarter 2017.**
- Successfully completing pre-clinical trials and moving to Phase 1 testing is an important step in the drug development process, and **typically acts as a significant share price catalyst.**



Based on a global antibiotic market of US$40bn (2014), we estimate the potential NPV of a royalty/licencing stream to RCE for its RECCE® antibiotics could be some US$400m (A$530m). At RCE's current diluted m'cap of A$28m, the market is valuing the group at (only) 5% of our NPV (i.e. the market has attached a 95% risk discount). **We believe that RCE offers exciting capital upside for speculative investors as the RECCE® antibiotic NPV is progressively de-risked. Lowering the discount to 90%, effectively doubles our indicative valuation to A$53m (A$0.52 per fully diluted share).**

Valuation

In 2010, health care providers in the US prescribed 258 million courses of antibiotics (equivalent to 833 prescriptions per 1,000 persons). Source: The New England Journal of Medicine, 2013.

Predicated on securing a royalty/licencing agreement with "Big Pharma" - one of several options RCE will be actively exploring to commercialise its IP - **we estimate the NPV of the US antibiotic market to RCE at ~US$180m (with a global NPV estimate closer to ~ US$400m)**. See table below.

We believe that the assumptions used in our NPV valuation are not unrealistic, and suggest that the resultant valuation illustrates the significant potential upside relative to RCE's current market capitalisation.

At the current spot US$0.77 exchange rate, our indicative valuation of US$412m equates to A$530m. Thus, at RCE's current (fully-diluted) market capitalisation of ~A$28m, we suggest that the market is only attaching a 5% probability that the RECCE® antibiotic product will achieve commercial success.

Indicative NPV valuation:

~US$400m

RCE: indicative NPV of RECCE® antibiotics (un-risked) (US$m)

	Development & FDA Approval						*Patents granted up to 2029 for Australia, USA,Europe, Japan , China and pending for ALL PCT Countries up to 2034*												
	2016	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**
No. of Prescriptions (million)	258	259	261	262	263	265	266	267	269	270	271	273	274	275	277	278	279	281	282
ARP per Prescription (US$)	50	51	52	53	54	55	56	57	59	60	61	62	63	65	66	67	69	70	71
Market value of Prescriptions (US$m)	12,900	13,224	13,556	13,896	14,245	14,602	14,969	15,345	15,730	16,124	16,529	16,944	17,369	17,805	18,252	18,710	19,180	19,661	20,155
% share RECCE antibiotic	na	na	na	na	na	na	1.0%	2.5%	3.5%	5.0%	5.0%	5.0%	5.0%	5.0%	2.5%	2.5%	2.5%	2.5%	2.5%
RECCE antibiotic Revenue (US$m)	0	0	0	0	0	0	150	384	551	806	826	847	868	890	456	468	480	492	504
Margin	na	na	na	na	na	na	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%	90%
Profit (US$m)	0	0	0	0	0	0	135	345	495	726	744	762	782	801	411	421	432	442	453
Royalty rate to RCE (%)	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%	12.5%
Royalty to RCE (US$m)	0	0	0	0	0	0	17	43	62	91	93	95	98	100	51	53	54	55	57
PAT (US$m)	0	0	0	0	0	0	12	30	43	63	65	67	68	70	36	37	38	39	40
Discount rate	*10%*																		
NPV - US market (US$m)	**183**																		
ROW as % US market	125%																		
NPV - ROW (US$m)	229																		
RECCE antibiotic NPV (Total) (US$m)	**412**																		

Source: State One Stockbroking forecasts

Key assumptions include:

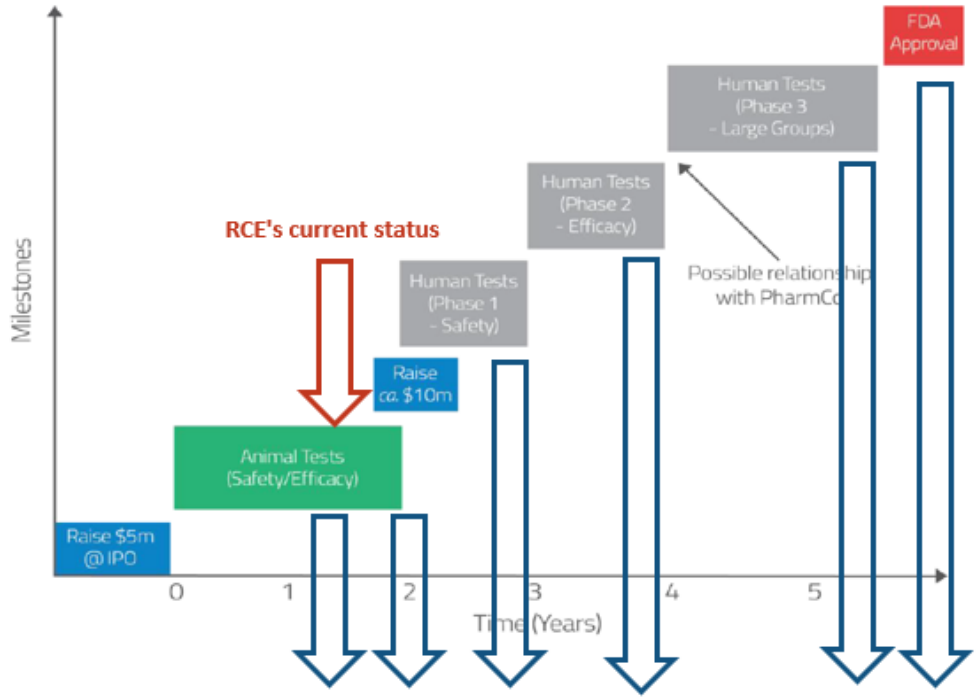
- ✓ 258m antibiotic prescriptions in the US in 2016 growing at 0.5%pa,
- ✓ Base-case average received price (ARP) of US$50 per prescription escalated at 2%pa,
- ✓ Production and sales of RECCE® antibiotic commencing in 2022 with 1% market share,
- ✓ Market share peaking at 5% by 2026, patents expiring in 2034 => 13 year patent protection from Year 1 production,
- ✓ 12.5% royalty rate to RCE,
- ✓ Rest of World (ROW) market at 125% of US market.

Note: We attribute zero value to the RECCE® antibiotic IP after 2034; we have not factored in 2016-2021 drug development costs (State One estimate: US$50m) or (off-setting) milestone payments over this development period.

Note: We do not attach any anti-cancer value to the RECCE® antibiotics. On 23 Feb, RCE announced that it was suspending its anti-cancer program to focus on commercialising its product(s) for antibiotic and anti-virus applications.

The high risk discount attached to RCE's valuation reflects the relatively early-stage nature of the group's product development - RECCE® antibiotics are (only) three quarters of the way through a program of animal tests for safety and efficacy, part of a longer-term six-year program to (final) FDA approval. However, we believe that as the development program progresses, RCE's share price should increase significantly as the probability of commercial success increases. See graph below.

Forecast RECCE® antibiotic development timeline and RCE indicative valuation



NPV- unrisked (A$m)	530	530	530	530	530	530
Risk discount (%)	95%	90%	80%	45%	30%	25%
NPV - risked (A$m)	27	53	106	292	371	398
NPV - risked (A$ per share)	**0.26**	**0.52**	**1.03**	**2.84**	**3.62**	**3.88**
Current share price (A$)	0.27	0.27	0.27	0.27	0.27	0.27
% upside / (downside)	na	92%	283%	953%	1241%	1336%

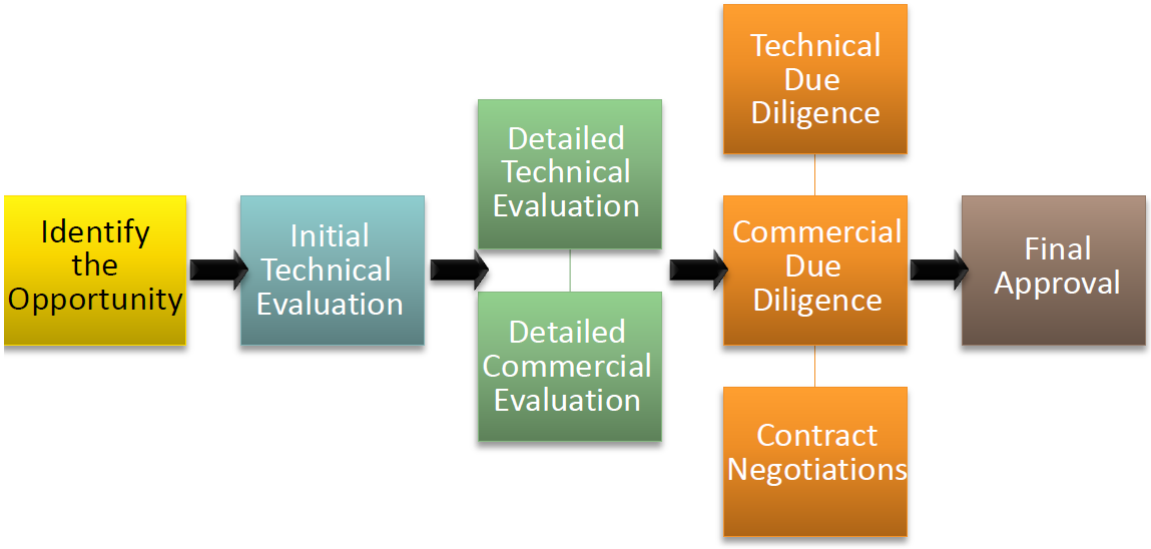
Source: Company, State One Stockbroking forecasts

- *At the start of Human Tests (Phase 1 - Safety), which are targeted for the December quarter 2017, we suggest a risk-adjusted valuation for RCE of A$53m (or A$0.52 per fully diluted share).*
- *If Human Tests (Phase 1- Safety) are successfully completed towards the end of 2018/beginning 2019, we suggest that RCE's risk-adjusted valuation could increase to A$106m (or A$1.03 per fully diluted share).*

Valuation risks

- Expenses and costs of 2016-2021 trials/development and compliance with regulations,
- High rate of failure for drug candidates (animals) proceeding through pre-clinical trials, and or failure/setbacks at any stage (Phase 1, 2,3) of the clinical trials (humans),
- Serious adverse events or safety risks could require Recce to abandon developments, and to preclude, delay, or limit approval of its products,
- Reliance on a relatively small number of key personnel,
- If Recce develops and manufactures the RECCE® antibiotic (versus selling the IP to Big Parma in exchange for a royalty), Recce will face the inherent risk of exposure to liability claims and regulatory action,
- The Company may be forced to litigate to enforce or defend its intellectual property rights,
- The Company may not be able to protect its proprietary technology in the marketplace,
- Competitors may be more successful than the Company,
- Failure to secure a Licencing/Royalty with one of the big PharmCos. The big players in the pharmaceutical industry have significant portfolios of early-stage/development prospects to evaluate; most prospects will not make it through the rigorous selection process. See graph below.

Licensing Process at Bristol-Myers Squibb



Source: Torreya Partners presentation, January 2014

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State One was Lead Manager for Recce Limited's IPO in January 2016.

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